REMARKS

Claims 1-6 are pending in this application. Claims 1 and 2 have been amended herein.

Claim 1 has been amended to recite "wherein said recombinant herpesvirus of turkeys does not comprise an HN gene". Support for this amendment may be found in the specification as follows. On page 3, line 15, to page 4, line 2, the specification discusses the prior art of WO99/18215 disclosing a recombinant of HVT having F and HN proteins of NDV. On page 4, line 4, the specification discusses difficulties associated with the goal of a vaccine which is "a recombinant virus expressing F protein gene", that is, "only F gene" (page 4, line 6) but not HN gene. The present specification clearly indicates that the NDV F gene is inserted into HVT, and it is clear from the description of the construction of the HVT on pages 7-8 of the specification, and in Figures 2 and 3, that no HN gene is inserted.

The amendment to claim 2 is for clarity, as discussed below.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite (Office action page 2).

Claim 1 is rejected because "the intended region or regions where the F protein [may be] inserted is not defined." The Examiner asks: "Is the intent to insert the F protein in essential regions of herpesvirus of turkey? This affects the dependent claims."

Reconsideration of the rejection of claim 1 is respectfully requested. Claim 1 requires "A recombinant herpesvirus of turkeys harboring an F protein gene of Newcastle disease virus ..." Here,

"harboring" must be taken to mean "comprising"; that is, the F protein gene sequence occurs in the claimed recombinant herpesvirus of turkeys. As such, Applicants submit that the claim is definite. The Examiner appears to be asking for further limitation on the location of the F protein gene sequence in the recombinant herpesvirus of turkeys, but such a further limitation is not necessary for the claim to be definite.

Applicants further submit that the Examiner's comment that "This affects the dependent claims" is unclear. None of the dependent claims mentions the term "essential regions". Applicants submit that claim 1, as amended, is also not indefinite.

Claim 2 is rejected for the recitation of "the non-coding, interORF region" of the backbone virus genome. The rejection is overcome by the amendment of claim 2. For clarity, claim 2 has been amended to read "a ~~the~~ non-coding, interORF region ...". The specification on page 6, last paragraph, lists several possible inter-ORF regions.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements (Office action page 2).

The Examiner indicates that "the omitted elements are: the antigens of "avian herpesvirus" wherein the protective immunity is induced against [sic] is/are not defined."

Reconsideration of this rejection is respectfully requested.

First of all, claim 4 specifically states that the protective immunity is being induced against avian herpesvirus and Newcastle disease virus. Applicants submit that this recitation is definite. With regard to the "antigens", Applicants note that claim 4 (as well as claims 1, 2 and 3) does not

use the term "antigen", and this term is not needed to define the claimed method. Therefore, Applicants respectfully submit that the Examiner's indication that claim 4 is omitting an element, is incorrect. Claim 4 recites a clearly stated method step ("inoculating the avian host with the recombinant herpesvirus") and is therefore definite.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps (Office action page 3).

The Examiner indicates that "the omitted steps are: when to apply the vaccine, how to apply the vaccine, the effective amount, etc..."

Reconsideration of the rejection is respectfully requested.

Applicants note, first of all, that there is really only one method step in claim 4, and therefore there is no "gap between the steps." Moreover, the "omitted steps" cited by the Examiner, **when** to apply, **how** to apply and the effective **amount**, are not steps at all but rather hypothetical additional limitations on the recited step. The lack of recitation of such limitations in the claim does not make the claim indefinite, and there is no requirement that these limitations be included in claim 4.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections (Office action page 3).

The Examiner states that "The omitted structural cooperative relationships are: the

relationship of Newcastle with other "avian herpesvirus antigens is/are not defined."

Reconsideration of the rejection is respectfully requested.

First of all, Applicants note that "avian herpesvirus antigens" are not even recited in the claims. The term "Newcastle disease" is recited in claim 4 only in the preamble, which states the utility for the recited method. This utility includes "inducing protective immunity ... against ...avian herpesvirus and Newcastle disease virus." Claim 4 recites a definite method step, as discussed above.

Secondly, Applicants submit that there is no need for the claim to in any way discuss the "relationship" between avian herpesvirus and Newcastle disease virus. Protective immunity against avian herpesvirus and Newcastle disease virus is the utility of the claim and is the result of carrying out the recited method step. Applicants note that, in fact, there is no requirement that the inventor of an invention even know the exact mechanism by which his invention works. (See 35 U.S.C. 103(a).) With regard to the Examiner's comment that "this affects claim 5", Applicants submit that claim 5 only limits claim 4 in limiting the route of inoculation, and that the relationship between avian herpesvirus and Newcastle disease virus is again irrelevant.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for turkey herpesvirus (VHT) having promoter identified as SEQ ID NO: 1 being capable of expressing F protein of Newcastle disease virus (NDV) being inserted into a region between UL45 and UL46 of HVT capable of inducing protective response against Newcastle disease virus, does not reasonably provide enablement for (1) insertion of F gene in

all regions of HVT in general, or "inter-Orf region" in particular (2) method of polyvalent vaccine wherein Newcastle disease virus as well as any and all antigens of avian herpesvirus are to induce protective response (Office action pages 3-5).

Reconsideration of this rejection is respectfully requested.

In **point (1)** of the rejection, the Examiner refers on page 4 to "suitable regions" for the insertion of F gene. Applicants note, however, that the specification on pages 6-7 implies that "non-essential regions" of HVT are where the NDV F gene should be inserted, and gives a clear description of how such a non-essential region can be identified. Applicants submit that the method disclosed on pages 6-7 clearly enables one of skill in the art to locate "suitable regions" for the insertion, and that this is consistent with the scope of the claims.

Moreover, the specification, starting on page 7, line 9, indicates that "any known method of generating the recombinant avian herpesvirus is applicable." The specification is clearly indicating that general methods of generating recombinant avian herpesvirus are known in the art, and that in the present invention, these methods can be modified to make recombinants with the recited "F protein gene of Newcastle disease virus under the control of a promoter of which sequence is shown in SEQ No. 1." That is, using the disclosure of the specification, known construction methods can be used without undue experimentation to produce the present invention as claimed.

The Examiner states that "Applicants own disclosure is used as evidence of the unpredictability of the field, see page 3 of the specification" (Office action page 4, line 8). It is not clear specifically what the Examiner is referring to, as page 3 of the specification never uses a term such as "unpredictability." The Examiner may be referring to the discussion of problems in the

function of the vaccines having F protein of NDV. For example, page 4, lines 6-8, indicates that rHVT having **only F gene of NDV** didn't induce desirable immunity in chickens ...." (emphasis added). However, this is not a discussion of the **present invention**, which has the promoter SEQ No. 1. Nowhere on page 3 or 4 of the specification is there any indication that there would be any undue experimentation necessary for the construction of a vaccine or a recombinant herpesvirus as recited in the present claims. That is, "unpredictability" is not an issue with respect to enablement of the present claims.

With regard to **point (2)** of this rejection, the Examiner indicates on page 4, line 11, that "there is no teaching presented for a method of polyvalent vaccine." However, Applicants are unclear whether by "method of polyvalent vaccine" the Examiner means "method of making a polyvalent vaccine" or the "method of using a polyvalent vaccine." In either case, Applicants respectfully disagree with this rejection. As discussed above, the specification clearly indicates the method of making the recombinant virus of claim 1. The specification also teaches how to inoculate chickens and to test for efficacy as a Newcastle disease vaccine.

The Examiner may to be referring on page 4, line 11, of the Office action to the fact that no specific method is disclosed in the specification to demonstrate efficacy against avian herpesvirus. However, one of skill in the art could readily determine the effectiveness of the vaccine against avian herpesvirus. Applicants submit that no undue experimentation would be required to isolate a recombinant HVT that is effective against both avian herpesvirus and Newcastle disease virus. In this regard, Applicants disagree with the Examiner's statement at the top of page 5.

Applicants further submit that the Examiner's comments about the "vector's backbone acting

as an antigen" (page 4, lines 12-20, of Office action) are not relevant. The mechanism of action of the vaccine is not at issue in this rejection. As long as one of skill in the art can follow the method disclosed in the specification and obtain a recombinant herpesvirus as claimed, the claims are enabled.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saito et al. (WO 99/18215) (Office action page 6).

Reconsideration of this rejection is respectfully requested in view of the amendment to claim 1.

To clarify the teachings of the cited reference, Applicants have obtained an English translation of the reference and have submitted this in the IDS accompanying this Amendment.

In the rejection, the Examiner refers to Saito et al. WO'215 on page 4, first full paragraph, and on page 7, as disclosing construction of turkey herpesvirus expression vectors by inserting antigens between UL45 and UL46. The Examiner also refers to the F antigen of Newcastle disease virus on page 9, at the bottom.

The Examiner then states the reference "taught utilization of a wide variety of promoters including the chicken beta-actin promoter that is now being claimed (see page 10, bottom of the page). This differs only with respect to modification of the promoter." The Examiner refers to page 5 of the present application, which states that the promoter used "is generated by deleting a dispensible region of the chicken beta-actin promoter."

The Examiner states "Applicants ... would have had access to the above teaching and the

cited patent taught all the elements that are utilized in the claimed invention except the modified promoter identified as SEQ. ID. NO. 1. However, given the level of skill in the art is high, the modification of the promoter is seen as **a design choice**, the skilled artisan would not have anticipated any unexpected results" (emphasis added).

As amended, claim 1 recites that "said recombinant herpesvirus of turkeys does not comprise an HN gene." However, the recombinant herpsevirus of turkeys of Saitoh et al. WO'215 has both the F and HN genes present. In order to modify the teaching of Saitoh et al. WO'215 to have the limitations of amended claim 1, it would be necessary not only to substitute the promoter of SEQ. ID. No. 1 for the promoter in the reference, but also to delete the HN gene in the disclosed recombinant. Applicants submit that Saitoh WO'215 does not disclose or suggest a herpesvirus of turkeys having the F gene and not having an HN gene.

Applicants also concur with the Examiner that SEQ. ID. NO. 1 is not taught in Saito et al. WO'215. Applicants submit, however, that the Examiner's indication that "this modification of the promoter is seen as a design choice" finds no basis in Saito et al. WO '215. This reference clearly cannot indicate that SEQ. ID. NO. 1 is in any way interchangeable with the promoters used in the reference, since SEQ. ID. NO. 1 is not mentioned in the reference.

Although not explicitly stated in the rejection, the suggestion to use the SEQ. ID. No. 1 promoter (Pec promoter) appears to have been derived from JP2001-000118, discussed in the specification on page 5. Applicants have cited this reference in the Information Disclosure Statement filed concurrently with this amendment, and have provided a complete translation. The reference does disclose use of the Pec promoter in a recombinant herpesvirus of turkeys; however, there is no suggestion in this reference to use the Pec promoter in a recombinant herpesvirus of

turkeys having the F protein gene but not the HN gene.

Applicants further submit that the effectiveness of the present vaccine is a surprising result. As noted in the specification on page 4, lines 5-7, in Morgan et al. (*Avian. Dis.* 37:1032-1040, 1993), rHVT having only the F gene of NDV didn't induce desirable immunity in chickens. That is, it is a surprising result that a recombinant herpesvirus having only the F gene of NDV can produce the desired immunity.

Applicants therefore submit that claims 1-6 are novel and non-obvious over Saito et al. (WO 99/18215).

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact Applicants undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

Attached hereto is a marked-up version of the changes made by the current amendment. The attached page is captioned "**Version with markings to show changes made**."

In the event that this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

ARMSTRONG, WESTERMAN & HATTORI, LLP

Daniel A. Geselowitz, Ph.D.
Agent for Applicants
Reg. No. 42,573

DAG/plb
Atty. Docket No. **020058**
Suite 1000
1725 K Street, N.W.
Washington, D.C. 20006
(202) 659-2930

23850
PATENT TRADEMARK OFFICE

Enclosures: Version with markings to show changes made

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend claims 1 and 2 as follows:

1. (Amended) A recombinant herpesvirus of turkeys harboring an F protein gene of Newcastle disease virus under the control of a promoter of which sequence is shown in SEQ No.1; wherein said recombinant herpesvirus of turkeys does not comprise an HN gene.

2. (Amended) A recombinant herpesvirus of turkeys as in claim 1 wherein the promoter and F protein gene are inserted into ~~the~~ a noncoding, inter-ORF region of the backbone virus genome.